IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
This document applies to: **WAVE 4 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION**	

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION TESTIMONY OF KONSTANTIN WALMSLEY, M.D.

Plaintiffs have identified Konstantin Walmsley, M.D. as their general-causation expert. Although Dr. Walmsley's two general-causation opinions are separately set forth in each of the three Rule 26 reports for the plaintiffs listed in Exhibit A,[1] the opinions are essentially identical, often verbatim, and are generally confined to the adequacy of the Instructions for Use (IFU) for the TVT and TVT-O products. If permitted, he will testify that IFUs did not reference certain conditions and therefore were "not sufficient to enable informed consent from the patient." Exs. B-D, Walmsley Reports, Gen. Op. 1. Second, he claims that Plaintiffs were unable to receive

[1] Dr. Walmsley's Rule 26 reports in these three cases—*Heidel*, *Ocker*, and *Plahmer*—contain no page numbers (*see* Ex. B, Walmsley *Heidel* Report (Heidel Report); Ex. C, Walmsley *Ocker* Report (Ocker Report); Ex, D, Walmsley *Plahmer* Report (Plahmer Report), but the first two opinions in each of the reports are identified as his general opinions (General Opinion No. 1 and No. 2). General Opinion No. 1 appears on pages 3-5 of the Heidel Report, pages 5-7 of the Ocker Report, and pages 4-5 of the Plahmer Report. General Opinion No. 2 appears on page 5 of the Heidel Report, page 7 of the Ocker Report, and page 6 of the Plahmer Report. The pages noted are those that would have existed if the report had been paginated.

"proper informed consent" because the IFUs did not inform of what Dr. Walmsley claims are safer alternative nonmesh procedures. *See, e.g.*, Exs. B-D, Walmsley Reports, Gen. Op. 2. Defendants Ethicon, Inc., Johnson & Johnson, and, if applicable, Ethicon LLC (Ethicon) ask that these opinions be excluded for the same reason that this Court excluded an almost identical opinion offered by Dr. Walmsley in the Wave 1 cases: he did not possess then, and still does not possess, the "additional expertise" to opine about what information should or should not be included in an IFU. *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4961675, at *3 (S.D.W. Va. Aug. 25, 2016) .

To the extent General Opinion No. 2 can be construed to also contain an opinion that safer alternative procedures existed to support a claim for design defect, that opinion too should be excluded as irrelevant.

ARGUMENTS AND AUTHORITIES

Ethicon incorporates by reference the standard for *Daubert* motions articulated by this Court in *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

I. Dr. Walmsley does not possess the required additional expertise to offer opinions on what should be included in the IFUs.

In General Opinion No. 1, Dr. Walmsley addresses the sufficiency of the IFU for the TVT products to enable informed consent to be given to the patient. Dr. Walmsley will testify that these IFUs do not include various risks, such as contraction, dyspareunia, mesh shrinkage, scar-plate formation, or difficulty removing the mesh if needed, which he claims makes informed consent impossible. *See* Exs. B-D, Walmsley Reports, Gen. Op. 1. Similarly, in General Opinion No. 2, Dr. Walmsley offers the opinion that the IFUs should have informed of allegedly "[s]afer alternative designs and procedures" that existed at the time. Exs. B-D, Walmsley Reports, Gen.

Op. 2. According to Dr. Walmsley, these "safer alternatives"—*i.e.*, autologous fascial slings—should have been included in the IFUs and without that information, the plaintiff "was unable to receive proper informed consent . . . ." *Id*.

Both opinions should be excluded because Dr. Walmsley is not qualified to offer them. As this Court has previously noted, although an expert who is a urologist or urogynecologist may testify as to the perceived risks to patients associated with the mesh product at issue and whether the IFU at issue conveyed those risks, the expert "must possess *additional expertise* to offer expert testimony about what information should or should not be included in an IFU." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4961675, at *3 (emphasis added); *see also Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *14 (S.D.W. Va. Feb. 7, 2015). This additional expertise includes experience with product labeling requirements (*Wise*, 2015 WL 521202, at *14) and the development of warning labels (*In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4961675, at *3; *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500767, at *4 (S.D.W. Va. Aug. 26, 2016) (excluding Dr. Blaivas's warnings opinions because he "is not an expert in the development of warning labels and thus is not qualified to offer expert testimony about warnings")).

Here, General Opinion No. 1 is identical to the one offered by Dr. Walmsley in the Wave 1 cases, which was excluded by this Court on the basis that Dr. Walmsley "does not possess the additional expertise to offer expert testimony about what an IFU should or should not include." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4961675, at *3. His General Opinion No. 2 similarly offers an opinion as to additional information that should have been included in the IFU for the TVT products. Exs. B-D, Walmsley Reports, Gen. Op. 2. Although Dr. Walmsley is a practicing urologist, he has no demonstrated expertise related to product

labeling requirements or the development of warning labels. In depositions taken in the Wave 3 cases, Dr. Walmsley admitted that he has never consulted with a device manufacturer as to the information to be included in an IFU, has never written or been asked to write an IFU, has never been asked to review an IFU for the United States Food and Drug Administration (FDA), and does not consider himself to be an expert in FDA medical device labeling requirements. *See* Ex. E, Walmsley 8/11/16 Dep. Tr. (*Baker*) 64:17-24; Ex. F, Walmsley 8/11/16 Dep. Tr. (*Ward*) 112:8-21. Accordingly, he is not qualified to offer either General Opinion No. 1 or 2 and this testimony should therefore be excluded.

II. The Court should exclude Dr. Walmsley's alternative-procedures opinions as irrelevant.

As demonstrated above, Dr. Walmsley's opinion regarding the availability of "alternative successful and safer sling procedures" at the time of Plaintiffs' implant surgeries is related to his opinions regarding what should be included in the respective TVT products' IFUs. *See* Exs. B-D, Walmsley Reports, Gen. Op. 2. To the extent, however, that General Opinion No. 2 can be construed to offer an opinion that safer alternative surgical *procedures* existed to treat stress urinary incontinence other than the TVT products, this opinion should be excluded. This is so because the autologous fascial sling—the alternative he proposes to the TVT products—is a *surgical procedure* and not a *medical device* (*see* Ex. G, Walmsley 8/17/16 Dep. Tr. (*Phillips*) 53:12-18), and evidence of an alternative surgical procedure cannot support a claim that an implantable medical device is defective in design as a matter of law (*e.g.*, *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (rejecting plaintiff's theory that defendant's spinal-fixation device was defective because there were alternative spinal-fusion procedures available that did not use spinal-fixation devices)).

This Court has already determined in mesh litigation that an alternative surgical procedure is not an alternative design and excluded such evidence as irrelevant. *See Mullins v. Johnson & Johnson*, No. 2:12-cv-02952, 2017 WL 711766, at *2 (S.D.W. Va. Feb. 23, 2017); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017) (excluding Dr. Goodyear's alternative-procedures opinion on relevancy grounds because "alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists"). Accordingly, to the extent General Opinion No. 2 asserts that the IFU needed to include a statement that safer alternative surgical procedures existed, that opinion should be excluded as irrelevant.

CONCLUSION

For the foregoing reasons, Dr. Walmsley's general-causation opinions—General Opinions No. 1 and 2 in these cases—should be excluded in their entirety. Further, to the extent General Opinion No. 2 is construed to support a claim for design defect, it too should be excluded.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 11, 2017, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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